

1. (Twice Amended) A method of treating Down Syndrome in a fetus by identifying and treating abnormal levels of a plurality of metabolites in a specimen of bodily fluid having metabolites from a patient, comprising:

obtaining a patient profile of all of the metabolites contained in the specimen by measuring the level of each of the metabolites in the specimen, wherein the patient profile comprises the level of each respective metabolite,

generating a control profile of the metabolites contained in the specimen, wherein the control profile comprises the level for normal patients of each respective metabolite in the patient profile, wherein the normal patients comprise patients who do not have Down Syndrome,

comparing the patient profile with the control profile by identifying each of the metabolites of the patient profile having a different level in comparison with the level of that metabolite for the control profile in order to identify a plurality of metabolites having different levels, wherein the comparing step comprises:

determining if a formiminoglutamic acid level of the patient profile is less than a formiminoglutamic acid level of the control profile to analyze a level of mono-carbon in the patient profile relative to a level of mono-carbon in the control profile,

determining if a homocysteine level of the patient profile is increased relative to a homocysteine level of the control profile to analyze the level of homocysteine in the patient profile,

determining if a normetanephrine level of the patient profile is increased relative to a normetanephrine level of the control profile to analyze the level of normetanephrine in the patient profile,

determining if an oxalic acid level of the patient profile is decreased relative to an oxalic acid level of the control profile to analyze a level of vitamin B6 in the patient profile relative to a level of vitamin B6 in the control profile,

determining if a serine level of the patient profile is decreased relative to a serine level of the control profile to analyze the level of serine in the patient profile, and

determining if a tetra-hydro-biopterin level of the patient profile is decreased relative to a tetra-hydro-biopterin level of the control profile to analyze the level of tetra-hydro-biopterin in the patient profile, and

prescribing a supplement for each respective metabolite of the plurality of metabolites of the patient profile having a different level when compared with the level of that metabolite for the control profile, wherein the supplement restores the level of the metabolite of the patient profile to the level of that metabolite for the control profile, and wherein the plurality of metabolites of the patient profile having different levels in comparison to the control profile identify a presence of Down Syndrome.

Please cancel claims 2-14 without prejudice.

Please add the following new claims 15-23.

15. (New) A method of identifying a presence of Down Syndrome in a fetus, comprising:
obtaining an amniotic fluid specimen by placing a syringe having a needle into a uterus and withdrawing the amniotic fluid specimen via the needle,

identifying a quantity for each metabolite that is present in the amniotic fluid specimen using a gas chromatograph/mass spectrometer,

compiling a patient profile, wherein the patient profile lists each metabolite and the quantity for each respective metabolite,

comparing the patient profile with a control profile, wherein the control profile lists the quantity for each respective metabolite of the patient profile that is present in persons without Down Syndrome, by comparing the quantity of each metabolite of the patient profile with the quantity for that respective metabolite of the control profile, and

identifying the presence of Down Syndrome in the fetus when a subset of metabolites of the patient profile has a different quantity than each respective metabolite of the control profile.

16. (New) The method of claim 15, wherein the subset of metabolites comprises formiminoglutamate, normetanephrine, homocysteine, oxalic acid, serine, and tetra-hydrobiopterin.

17. (New) The method of claim 15, further comprising prescribing a supplement for each respective metabolite of the subset of metabolites of the patient profile having a different quantity when compared with the quantity of that metabolite for the control profile, wherein the supplement restores the quantity of the metabolite of the patient profile to substantially the quantity of that metabolite for the control profile.

18. (New) The method of claim 15, wherein the quantity for each respective metabolite listed by the control profile comprises a mean level.

19. (New) The method of claim 15, wherein the quantity for each respective metabolite listed by the control profile comprises a median level.
20. (New) The method of claim 15, further comprising, after the obtaining an amniotic fluid specimen step, storing the amniotic fluid specimen at around -20° C.
21. (New) A method of identifying a presence of Down Syndrome in a fetus, comprising:
 - obtaining an amniotic fluid specimen by placing a needle into a uterus and withdrawing the amniotic fluid specimen via the needle,
 - identifying a quantity for each metabolite that is present in the amniotic fluid specimen by analyzing the amniotic fluid specimen using a gas chromatograph/mass spectrometer,
 - compiling a patient profile, wherein the patient profile lists each metabolite and the quantity for each respective metabolite present in the amniotic fluid specimen,
 - obtaining a control profile, wherein the control profile lists a quantity for each metabolite present in the amniotic fluid specimen for a population of patients without Down Syndrome.
 - identifying a plurality of abnormal quantities of metabolites of the patient profile by comparing the quantity of each metabolite of the patient profile with the quantity for that respective metabolite of the control profile, and
 - identifying the presence of Down Syndrome in the fetus when the plurality of abnormal quantities of metabolites of the patient profile corresponds to abnormal quantities of those metabolites in a patient known to have Down Syndrome.

22. (New) The method of claim 21, wherein the plurality of abnormal quantities of metabolites of the patient profile comprises decreased formiminoglutamic acid, increased homocysteine, increased normetanephrine, decreased oxalic acid, decreased serine, and decreased tetra-hydro-biopterin.

23. (New) The method of claim 21, wherein the plurality of abnormal quantities of metabolites of the patient profile consists of at least two abnormal quantities chosen from the group consisting of decreased formiminoglutamic acid, increased homocysteine, increased normetanephrine, decreased oxalic acid, decreased serine, and decreased tetra-hydro-biopterin.

REMARKS

In the Office Action dated June 20, 2001, the Examiner rejected claims 1-14 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 2-14 have been canceled. Also, Applicant has amended claim 1 to address the Examiner's rejection of that claim under 35 U.S.C. § 112, second paragraph.

The Examiner also rejected claim 1 under 35 U.S.C. § 103(a) as unpatentable over the Hoffmann and Galjaard references. The Examiner also withdrew the former rejection of claim 4 as unpatentable over the Hoffmann and Galjaard references. In response, Applicant has amended claim 1 to include the limitations contained in claim 4, and has canceled claim 4. Applicant has also added new claims 15-23.